REMARKS

STATUS OF THE CLAIMS

Claims 2-12 were pending in this application. Claims 2, 3, and 4 have been amended. Following entry of the amendments claims 2-12 will be pending and at issue.

SUPPORT FOR AMENDMENTS TO THE CLAIMS

Claim 2 has amended to replace the term "array" with the term "gene expression microarray." Support for this amendment can be found in throughout the specification as filed, e.g., at page 2, line 11 ("The present invention addresses the need for improved methods for analysis of micro-array derived gene expression data ...") and line 17 ("Methods are provided for determining the precision of data obtained from nucleic acid array, including gene expression microarrays ...").

Claims 3 and 4 have been amended to more clearly define the parameter c as a parameter that is set at 2, 2.5 or 3 for each iteration of the thresholding algorithm. Support for this amendment can be found in throughout the specification as filed, e.g., at page 11, line 13 ("Calculate the cutoff point, $u_0 = MAD_0 + (c \times s_0)$, where $s_0 = MAD_0/0.675$ and $c = 2, 2.5,$ or 3 (i.e., the number of median absolute deviations above the median)").

The amendments to the claims therefore add no new matter and entry is respectfully requested.

Applicant notes that the claim amendments should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 3 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant respectfully points out that this rejection was already made in the Office Action mailed 01/16/04 and was successfully argued in the Response filed 06/16/04 as the rejection was withdrawn in the Office Action mailed 09/09/04. In order to expedite prosecution, Applicant repeats the arguments previously presented and has amended the claims.

In paragraph 7 of the 03/04/05 Office Action, the Examiner states that

> Claims 3 (c) and 4, (c), recite the limitation of "c" wherein c is within the range of 2 and 3. However, the claims do not recite any limitations which define the variable "c". Further, the specification on page 11 recites a step for calculating "c=2, 2.5, or 3." However, the instant specification does not provide any direction by guidance or working examples as to how the value for "c" had been determined to be used in the claimed method..

Applicant respectfully points out that the parameter c is not "determined" or "calculated" but rather selected anew with each iteration of the thresholding algorithm. The parameter c is the number of standard deviations above the mean or median and is used in a thresholding algorithm to determine the cutoff point. (Specification, page 10, lines 4-7). The cutoff point is the expression measurement below which the analyst decides to not analyze data, e.g., expression measurements below the cutoff point are assumed to be unreliable and/or noise specific to the array.

For the purposes of the invention, c can be set at 2, 2.5 or 3 for each iteration of the thresholding algorithm. (Specification, page 11, lines 12-14). These values for c are reasonable given that, e.g., it has been suggested that genes exhibiting at least 3-fold changes in differential expressions in cDNA arrays are deemed significant. Which value of c (e.g., 2, 2.5, or 3) is selected by the analyst depends on the desired stringency of the gene expression experiment.

Without agreeing with the Examiner's position, Applicant has amended claims 3 and 4 to recite that _c is the number of standard deviations or mean absolute deviations above the mean or median and c is set at 2, 2.5 or 3 for each iteration of the thresholding algorithm._ With this amendment, "c" is more clearly defined and Applicant requests withdrawal of this rejection.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 2, 5-8, and 10 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Rocke et al. (1995) taken with Bailey et al. (1987). Without agreeing with the Examiner's position, Applicant has amended claim 2 to replace the term "array" with the term "gene expression microarray." The element of a gene expression

microarray cannot be found in either Rocke et al. (1995) or Bailey et al. (1987). The cited prior art references do not teach all of the elements of the claims as amended and the combination cannot render the claims obvious. Withdrawal of this rejection is respectfully requested.

STATEMENT OF SUBSTANCE OF EXAMINER INTERVIEW

Applicant thanks the Examiner for his time during a telephone interview on Tuesday June 14, 2005. Present for the interview were Examiner Choon Ly and Applicant's representative, Patent Agent Susan Hubl. No exhibits or demonstrations were presented or discussed. During the interview, claims 2, 3, and 4 were discussed.

Patent Agent Hubl indicated that claim 2 might be amended to recite "gene expression microarray" instead of "array" in order to overcome the 103 rejection citing Rocke and Bailey as neither Rocke nor Bailey teach or suggest using data from gene expression microarrays. Examiner Ly indicated that he would consider the amendment and that it was possible that the amendment would overcome the rejection. Examiner Ly noted that he would require specific support in the specification for the amendments.

Patent Agent Hubl indicated that claims 3 and 4 might be amended to more clearly define the parameter "c" as described in the specification on pages 10 and 11 in order to overcome the 112, first paragraph enablement rejection. Examiner Ly indicated that he would consider the amendment and that it was possible that the amendment would overcome the rejection.

CONCLUSION

Withdrawal of the pending rejections and reconsideration of the claims are respectfully requested, and a notice of allowance is earnestly solicited. If the Examiner has any questions concerning this Response, the Examiner is invited to telephone Applicant's representative at (415) 875-2316.

Respectfully submitted,

DAVID M. ROCKE ET AL.

Dated: _____7/5/05_____   . By: _____Λ Hubl_____

Susan T. Hubl, Ph.D. Patent Agent
Reg. No.: 47,668
Fenwick & West LLP
Silicon Valley Center
801 California Street
Mountain View, CA 94041
Tel.: (415) 875-2316
Fax.: (650) 938-5200